SEP 2 7 2004

SEP 3 0 2004 PTO/SB/21 (04-04) Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
the Paperwork Reduction Act of 1995, no persons are required to restrict to a collection of information unless it displays a valid OMB control number. **Application Number** 09/688076 Filing Date **TRANSMITTAL** October 13, 2000 First Named Inventor **FORM** Philip A. Beachy Art Unit 1623 (to be used for all correspondence after initial filing) **Examiner Name** Patrick. T. Lewis Attorney Docket Number JHUC-P01-016 Total Number of Pages in This Submission ENCLOSURES (Check all that apply) After Allowance communication Fee Transmittal Form Drawing(s) to Technology Center (TC) Appeal Communication to Board of Licensing-related Papers Fee Attached Appeals and Interferences Appeal Communication to TC Amendment/Reply (Appeal Notice, Brief, Reply Brief) Petition to Convert to a Proprietary Information After Final **Provisional Application** Power of Attorney, Revocation Status Letter Affidavits/declaration(s) Change of Correspondence Address Other Enclosure(s) (please Extension of Time Request Terminal Disclaimer Identify below): Supplemental IDS Form SB/08 Request for Refund Express Abandonment Request One Reference Return Receipt Postcard Supplemental Information CD, Number of CD(s) Disclosure Statement (2 pages) Certified Copy of Priority Document(s) Remarks Response to Missing Parts/ Incomplete Application Response to Missing Parts under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm ROPES & GRAY LLP David P. Halstead - 44,735 Individual name Signature

| Date | September 23, 2004 |
|-----------------------------------|---|
| | |
| I hereby of an enveloped shown be | certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in pe addressed to: MS Amendment, Commissioner to Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date low. G-33-04 Signature: (Dawn Class) |
| 9544012- ⁻ | |

PTO/SB/17 (10-03) Approved for use through 7/31/2006. OMB 0651-0032

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| PEE TRANSMITTAL | | Application Number | | | 09/688076 | | | |
| for FY 2004 | | Filing Date October 13, 2000 | | | 3, 2000 | | | |
| | | First Named Inventor Philip A. Beachy | | | Beachy | | | |
| Effective 10/01/2003. Patent fees are subject to annual revision. | | Examiner Name Patrick T. Lewi | | | Lewis | | | |
| Applicant claims small entity status. See 37 CFR 1.27 | | Art Unit 1632 | | | | | | |
| TOTAL AMOUNT OF PAYMENT (\$) 180.00 | | | | ket No |). | JHUC-P0 | 1-016 | |
| METHOD OF PAYMENT (check all that apply) | | | | | | ATION (cor | ntipued) | |
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| X Deposit Account: | • | Large Entity Small Entity | | | | | | |
| Deposit 18-1945, Account 18-1945, | Fee | Entity Fee | Fee | Fee | • | F D | | |
| Number Under Order No. JHUC-P01-016 | Code | (\$) | Code | (\$) | | Fee Desc | ription | Fee Paid |
| Deposit Account Ropes & Gray LLP | 1051 | 130 | 2051 | 65 | Surcharge - | - late filing fee | or oath | |
| Name | 1052 | 50 | 2052 | 25 | | - late provisio | nal filing fee or cover | |
| The Director is authorized to: (check all that apply) | 1050 | 420 | 1053 | 120 | sheet. | h annai# | | |
| X Charge fee(s) indicated below X Credit any overpayments | 1053 | 130 | 1053 | | • | h specification | | |
| X Charge any additional fee(s) or any underpayment of fee(s) | 1812 | 2,520 | 1812 | | - | | arte reexamination | |
| Charge fee(s) indicated below, except for the filing fee | 1804 | 920* | 1804 | 920" | Examiner a | publication of ction | • | |
| to the above-identified deposit account. | 1805 | 1,840* | 1805 | 1,840* | Requesting Examiner a | publication o | f SIR after | |
| FEE CALCULATION | 1251 | 110 | 2251 | 55 | | or reply within | first month | |
| 1. BASIC FILING FEE | 1252 | 420 | 2252 | 210 | Extension for | or reply within | second month | |
| Large Entity Small Entity | 1253 | 950 | 2253 | 475 | | or reply within | | |
| Fee Fee Fee Fee Fee Description Fee Paid Code (\$) Code (\$) | 1254 | 1,480 | 2254 | 740 | Extension f | or reply within | fourth month | |
| 1001 770 2001 385 Utility filing fee | 1255 | 2,010 | 2255 | | | or reply within | fifth month | |
| 1002 340 2002 170 Design filing fee | 1401 1402 | 330 330 | 2401 | | Notice of Ap | ppeal of in support of | on nepeal | |
| 1003 530 2003 265 Plant filing fee 1004 770 2004 385 Reissue filing fee | 1402 | 290 | 2402 | | - | oral hearing | an appear | |
| 1005 160 2005 80 Provisional filing fee | 1451 | 1,510 | 1451 | | - | - | ic use proceeding | |
| SUBTOTAL (1) (\$) 0.00 | 1452 | 110 | 2452 | 55 | Petition to r | evive – unavo | oidable | |
| 30B101AL (1) (4) 0.00 | 1453 | 1,330 | 2453 | 665 | Petition to r | evive - uninte | ntional | |
| 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE Extra Fee from | 1501 | 1,330 | 2501 | | · | fee (or reissu | e) | |
| Claims below Fee Paid | 1502 | 480 | 2502 | | Design issu | | | |
| Total Claims = x = x | 1503 | 640 | 2503 | | Plant issue | | | <u> </u> |
| Claims L X L X | 1460 | 130 | 1460 | | | the Commiss | | ļ |
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| Large Entity Small Entity Fee Fee Fee Fee Fee Fee Fee Fee Fee Fe | 1806 | 180 | 1806 | | | | n Disclosure Stmt ssignment per | 180.00 |
| Code (\$) Code (\$) | 8021 | 40 | 8021 | 40 | property (tir | nes number d | f properties) | |
| 1202 18 2202 9 Claims in excess of 20 | 1809 | 770 | 2809 | 385 | (37 CFR 1. | | final rejection | |
| 1201 86 2201 43 Independent claims in excess of 3 1203 290 2203 145 Multiple dependent claim; if not paid | 1810 | 770 | 2810 | 385 | | dditional inver | | |
| 1204 86 2204 43 ** Reissue independent claims | 1801 | 770 | 2801 | 385 | | 37CFR 1.129 r Continued E | (0)) xamination (RCE) | |
| over original patent | 1802 | 900 | 1802 | 900 | | r expedited ex | amination | |
| 1205 18 2205 9 ** Reissue claims in excess of 20 and over original patent | | fee (spe | l | | of a design | application | | |
| SUBTOTAL (2) (\$) 0.00 | | uced by | | ling Fee | Paid | SUBTO | TAL (3) (\$) | 180.00 |
| **or number previously paid, if greater; For Reissues, see above | | | | | | | 1-7 | |
| SUBMITTED BY | | | | | | (Complete | (if applicable)) | |
| Name (Print/Type) David P. Halstead | | tration No ey/Agent | | ,735 | | Telephone | (617) 951-7615 | |
| Signature / 3 | Transiti | -yrrigorit, | | | | | September 23, | |
| M M | | | | | | لـــــــــــــــــــــــــــــــــــــ | | |
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| an envelope addressed to: MS Amendr | ment, Commissioner for Parents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date |
| shown below. | Sizzani V Mun Class (DAMANARIE CLASS) |
| 9-23-04 | OF THE STATE OF ASSISTANCE OF |

Dated: 9-23-04 Sig

(Dawn Class)

Docket No.: JHUC-P01-016

(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Beachy et al.

SEP 3 0 2004

Application No.: 09/688076

Confirmation No.: 8453

TECH CENTER 1600/2900

Filed: October 13, 2000

Art Unit: 1623

For:

REGULATORS OF THE HEDGEHOG PATHWAY, COMPOSITIONS AND USES

RELATED THERETO

Examiner: Patrick T. Lewis

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

MS Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the reference listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Supplemental Information Disclosure Statement is filed more than three months after the U.S. filing date, OR more than three months after the date of entry of the national stage of a PCT application, AND after the mailing date of the first Office Action on the merits, whichever occurs first, but before the mailing date of a Final Office Action or Notice of Allowance (37 CFR 1.97(c)).

A copy of each reference on the PTO/SB/08 is attached.

In accordance with 37 CFR 1.97(g), the filing of this Supplemental Information

Disclosure Statement shall not be construed to mean that a search has been made or that no other

Application No.: 09/688076 Docket No.: JHUC-P01-016

material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Supplemental Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Supplemental Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed reference.

Please charge our Deposit Account No. 18-1945, under Order No. JHUC-P01-016 in the amount of \$180.00 covering the fee set forth in 37 CFR 1.17(p). The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 18-1945, under Order No. JHUC-P01-016.

Dated: September 23, 2004

Respectfully submitted,

David P. Halstead

Registration No.: 44,735

ROPES & GRAY LLP

One International Place

Boston, Massachusetts 02110-2624

(617) 951-7000

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(617) 951-7050 (Fax)

Attorneys/Agents For Applicant



PTO/SB/92 (08-03)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Application No. (if known): 09/688076

Attorney Docket No.: JHUC-P01-016

Certificate of Mailing under 37 CFR 1.8

SEP 3 0 2004

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on September 23, 2004 Date

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IDS Form SB/08 (1 Reference)

SEP 3 0 2004

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Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/B/PTO

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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| Complete if Known | | | | |
|------------------------|-------------------|--|--|--|
| Application Number | 09/688076 | | | |
| Filing Date | October 13, 2000 | | | |
| First Named Inventor | Philip A. Beachy | | | |
| Art Unit | 1623 | | | |
| Examiner Name | Patrick. T. Lewis | | | |
| Attorney Docket Number | JHUC-P01-016 | | | |

| | U.S. PATENT DOCUMENTS | | | | | | |
|-----------------------|-----------------------|--|--------------------------------|--|--|--|--|
| Examiner Initials* | Cite No.1 | Document Number Number-Kind Code ² (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant | | |
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| | FOREIGN PATENT DOCUMENTS | | | | | | | |
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| Examiner Initials* | Cite No.1 | Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁸ (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | ۳° | | |
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| | | NON PATENT LITERATURE DOCUMENTS | |
|----------------------|--------------|--|----|
| Examiner Initials | Cite No.1 | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T² |
| | BJ | Mistretta, Charlotte et al., "Cyclopamine and jervine in embryonic rat tongue cultures demonstrate a role for Shh signaling in taste papilla development and patterning fungiform papillae double in number and form in novel locations in dorsal lingual epithelium," Developmental Biology, 2003, pp. 1-18, 254. | |

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.